COVINGTON & BURLING

CONFIDENTIAL

June 18, 1981

To: Messrs. Crohn
Greer
Henson
Holtzman
Pepples
Stevens

Re: Meeting at HHS with Secretary Brandt

Yesterday afternoon Horace Kornegay and I met with Assistant Secretary for Health Edward N. Brandt, Jr., John Pinney, director of the Clearinghouse on Smoking and Health, Joann Luoto, M.D., medical adviser to Pinney's office, and Richard Riseberg, an HHS attorney. (Pinney, Luoto and Riseberg were the three other HHS participants in our meeting with Assistant Secretary Richmond held on December 18, 1980.) The meeting, held in Secretary Brandt's office, started at about 5:10 p.m. and lasted slightly more than an hour.

At the outset of the meeting Horace Kornegay mentioned that we were here to continue the discussion on behalf of the cigarette companies, and that we hoped that a satisfactory basis for cooperation could be developed. Secretary Brandt and Pinney each emphasized the HHS desire to work out some type of voluntary agreement which would be satisfactory both to HHS and to the cigarette companies. Secretary Brandt said that they were interested in obtaining (1) a list of additives used in cigarettes manufactured in the United States, together with the amounts of such additives contained on some standard basis (e.g., by amount per cigarette or per carton); and (2) the results of any toxicity testing the companies have already done on these ingredients. According to the Secretary, after obtaining this information, the HHS plan would be to have a panel of experts review the material received from the industry, as well as other information available from published literature, and advise whether any of the substances on the list, in the view of the experts, presented public health problems.

We made the point that the formulas of particular brands of cigarettes were closely guarded and extremely important trade secrets and that we strongly urged that the HHS representatives approach the matter by reducing to the minimum

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possible the type of information requested. We emphasized that this was particularly important since we were satisfied that HHS could not give us completely satisfactory guarantees of confidentiality, in view of possible Freedom of Information Act requests and other factors that could be beyond the Department's control. In addition, beyond the question of confidentiality, we wanted to be certain that there would be fair treatment and proper handling of any information; we expanded on this by stating that we would not want HHS to be going public and certainly did not want any replays of the "shellac" incident. We also stated that we wanted to have a clear idea of what HHS intended to do after receiving the advice of the panel of experts. The discussion on these matters ended up as follows:

I. List of Substances

HHS would be satisfied with a composite list of ingredients which could be compiled from information submitted by the individual companies to, for example, Covington & Burling or an accounting firm such as Price Waterhouse.

Question of "commonly added"

We took the position that we were not quite sure how pervasive the use of a particular substance would have to be, to be considered "commonly added," but that we assumed unless it was used by several of the companies, it would not come within that terminology. On this score Pinney said that he knew we placed weight on the term "commonly added," but that he would hope that any list would be made as all-inclusive as possible. He further added that, at a minimum, if the companies were not prepared to give an inclusive list, he would hope to have some indication of the number and types of substances excluded from the list. In this area, Dr. Luoto said that another factor in considering what is "commonly added" should be the amount of the substance involved. In her view, even if only one company used an ingredient but it was used in substantial amounts, that factor should bring it within the concept of being "commonly added."

Possible cut-off date

We made the point that HHS had been taking the position that additives may present a problem because of their use in low-tar and nicotine cigarettes and that it would make sense to compile a list of substances used for the first time after 1965 or some later date. In this connection, we stated

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that the whole concept of additives as a problem seemed to be grossly inflated because, as we understood it, there were probably smaller amounts of substances added to low-tar cigarettes rather than to the traditional cigarettes. In fact, we observed, there have been suggestions that this new interest in additives might well be the result of searching for new projects for the Clearinghouse, rather than because of any legitimate basis for concern.

Although Secretary Brandt at first indicated that perhaps the list could be cut off to substances added for the first time since 1965 or later, his final observation was that they simply did not know enough about what was added to cigarettes to know whether the request could be truncated or limited. Pinney and Luoto clearly did not want to limit the request to 1965 or some similar cut-off date. As an argument against this, Pinney said that one of the problems with the Hunter Committee list was that a number of items had been grandfathered because they reportedly had been used for a long period of time; that HHS had shown the Hunter list to several toxicologists, and that they had raised health concerns about a number of items on the Hunter Committee list that had been in long-time use.*/

Pinney felt constrained to answer our suggestion that the additives inquiry was to give a new project to the Clearinghouse. He said that, as he had pointed out at the December 1980 meeting with then Secretary Richmond, they felt there was a legitimate public health concern in the question as to what substances were being added in the manufacture of cigarettes and whether any of these substances presented adverse health consequences beyond those which they viewed as being generally caused by smoking. Pinney and Luoto said that this meant any increased risk either by adding to what they viewed as the general risk in smoking or by possibly presenting some different health problems. Pinney said that their preliminary work clearly suggested that some additives could present such problems and that their interest in additives "was not a gimmick."

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*/ In discussing the Hunter list and the procedures followed by the British, Pinney mentioned that under the British program new substances could not be used in cigarettes unless certain procedures were followed to establish that they did not present special health problems. We did not engage in any discussion of this point.

Expanding on the question of additives that may have been in long-term use, Pinney again mentioned powdered cocoa which he said is banned by the British. He said the experts they have spoken to state that cocoa is a known animal carcinogen when burned. He added that United States cigarette manufacturers buy more powdered cocoa than any other industry in the United States. When Pinney brought up the use of powdered cocoa and mentioned that tests had shown that this ingredient presented a problem, we mentioned that we assumed he was referring to the work that came out of the Gori group and that it was our understanding that the industry did not agree with the conclusions there reached.

Dr. Luoto also mentioned, as examples of suspect ingredients, glycerol and eugenol. (At the conclusion of the meeting she gave me the attached copy of an article from Chemical Marketing Reporter of April 6, 1981, which appears to be the basis for some of her views.) In similar vein, Pinney said that they had reviewed the Hunter Committee list with Fred Bock (who we understand is at Roswell Park Institute), Dietrich Hoffman (an associate of Ernest Wynder at the American Health Foundation), and at least one other person who may well have been Jesse Steinfeld. Pinney said that this is the group that said that some items on the Hunter list have possible adverse health significance.

II. Handling of Information And "Fair Treatment" in Its Use

Both Secretary Brandt and Pinney said that there should be no "going public" or leaking information and that there should be no reason to have any incident such as the shellac situation repeated. They both agreed that if information is to be furnished, the initial discussion of questions about any substance and what further had to be done should be with the industry.

Pinney went on to reiterate that they were talking about and hoping to work out a voluntary program. He suggested that, if we desired, we could prepare a proposal stating that we would agree to furnish certain information only under certain clearly specified conditions and, unless these conditions were agreed to by HHS, we would not enter into a voluntary program. In addition, Pinney said that if it were helpful, arrangements might be made to have the HHS people view the list at the Covington & Burling or accounting firm offices and not to take any copies to HHS.

III. Question of Further Action after Material Is Reviewed by HHS-Constituted Panel of Experts

Secretary Brandt said that he anticipated that many of the substances on any list will turn out to be "common enough" so that there will be no concern about them. As an example, he mentioned menthol. He also said that he would assume that the companies must have done some toxicity testing that should be helpful; he assumed that a company would not add an ingredient without satisfying in some way that it did not present problems, if only to make sure that it was not going to flash up in flame. He said it might well be however, that some number -- perhaps one or two dozen -- might need testing.

Brandt agreed with our observations that any question of testing presented serious problems, as to cost, availability of testing facilities, and time.

After stating that neither Horace nor I was privy to the operations of any of the companies, we said we felt confident that they look carefully at any substance added to their cigarettes but that we would be flabbergasted if each substance added to cigarettes was subject to testing by inhalation tests or other complicated, expensive and time consuming procedures. Put bluntly, we stated, we wanted to make it clear that the companies were not interested in trying to cooperate in an effort to establish a "special FDA-type procedure for cigarettes," and that we did not believe they would cooperate in the program if it was being used as a vehicle to try to introduce an extensive testing program for a large number of cigarette ingredients.

Brandt and Pinney both disclaimed any objective of this type and said that the question of testing relates to additives which could present special or additional health consequences. Brandt also said that they wanted to use a carefully phased, deliberate approach and did not want to make any decisions at this time on what, if any, testing was necessary. What he was now interested in was working out a voluntary arrangement for the providing of a list of ingredients, and underlying information on them.

Riseberg made his only comment toward the end of the meeting. He said that, if only a composite list of "commonly used" ingredients was involved, there should be no confidentiality issue in the basic sense of trade secrets

but only our concern about unfair or premature publicity. Our response was that the trade secret problem would be minimized but that some questions in this area might still persist.

As the meeting broke up, Pinney said that he hoped a satisfactory voluntary plan could be evolved because they were under continuing pressure from the voluntary health associations to take some action on additives. Pinney added that they had assured the voluntary health groups that the industry had been negotiating in good faith with the Department, and that the Department was hopeful that some voluntary agreement could be reached.

We told the HHS representatives that we would have to report to the companies and that we would then get back in touch with them.

Stanley L. Temko